IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

DEBBY L. OTTE,

Plaintiff,

v.

BAXTER HEALTHCARE CORPORATION, ET AL.,

Defendants.

Civil No. CCB-00-910

JOINT PROPOSED SCHEDULING PLAN

Defendants Baxter Healthcare Corporation and Allegiance Healthcare Corporation and Plaintiff Debby L. Otte hereby submit their Joint Proposed Scheduling Plan in response to this Court's July 2, 2003 Order.

A. DESCRIPTION OF THE CASE

1. Concise Factual Summary of Plaintiff's Claims/Defenses:

[To Be Provided By Plaintiff's Counsel]

2. Concise Factual Summary of Defendants' Claims/Defenses:

Plaintiff Debby L. Otte alleges that she developed a natural rubber latex allergy during her career as a Medical Secretary from use and exposure to natural rubber latex gloves ("NRL gloves") manufactured by the defendants in this matter. Plaintiff also alleges that, as a result of her latex allergy, she became unable to work in any environment containing latex products.

Defendants deny plaintiff's allegations. Defendants contend that there is no evidence that plaintiff was injured by or as a result of any glove manufactured by them. Defendants also contend that their NRL gloves were not defective. Defendants further allege that plaintiff's latex

allergy is either nonexistent or that her symptoms are attributable to her history as a smoker, her allergies to other allergens or her various work-related injuries over the years. Moreover, defendants will show that plaintiff's claims are barred by the applicable statute of limitations. In addition, defendants will show that plaintiff's alleged latex allergy has not prevented or limited plaintiff's ability to work.

The foregoing defenses involve numerous case-specific issues for which discovery was not permitted in the MDL. Discovery completed in the MDL included only written discovery and document production. Additional discovery, including but not limited to the remainder of plaintiff's deposition, as well as depositions of plaintiff's co-workers and supervisors, witnesses to her alleged allergic reactions, treating physicians, and expert discovery remains to be completed.

For the Court's convenience, defendants have attached hereto, as an Addendum, a short historical account of this natural rubber latex glove litigation.

B. DISCOVERY PLAN

The parties recommend that the Court adopt discovery procedures as follows:

1. Rule 26(a)(1) Disclosures

The parties agree that Rule 26(a)(1) disclosures are deemed served as a result of discovery already completed in MDL 1148.

2. The parties agree that discovery should be limited to case-specific issues.

3. Motions for Amendments to Pleadings/Joinder of Additional Parties

Any motions for amendments to pleadings or joinder of additional parties shall be filed no later than August 15, 2003. Any such motions to be heard on or before September 1, 2003.

4. Deadlines for completion of expert witness discovery

a. Plaintiff shall provide defendants with any and all expert reports, in accordance with F.R.C.P. Rule 26(a)(2), including those of treating physicians to be called as experts, no later than August 15, 2003.

b. Defendants shall complete depositions of plaintiff's experts by October 15, 2003.

c. Defendants shall provide plaintiff with any and all expert reports no later than November 1, 2003.

d. Plaintiff shall complete depositions of plaintiff's experts by December 31, 2003.

5. Each expert may be deposed only on case-specific issues. Depositions of generic experts, including in the areas of manufacturing*, warnings, epidemiology and regulatory were completed in the MDL (*defendants dispute the characterization of manufacturing as a generic issue). As such, no depositions of generic experts or on generic issues will be permitted.

6. Factual Depositions

a. Plaintiff had the opportunity to take depositions of the defendants in the MDL. Therefore, no further depositions of the defendants will be permitted without leave of Court.

b. Defendants will be permitted to depose all remaining case-specific witnesses, including but not limited to the plaintiff and all non-party fact witnesses, including the plaintiff's treating physicians. If the parties learn that a witness within the subpoena power of the Court will be unavailable for trial, a trial deposition may be noticed and taken of such witness.

7. Requests for Admissions

Each party is permitted 20 requests for admissions. Each party may serve requests for admission no later than December 1, 2003. Responses to requests for admission, including objections thereto, shall be served no later than 30 days thereafter in accordance with F.R.C.P. 36(a).

8. Rule 35 Examinations

All Rule 35 Examinations shall be completed by October 1, 2003.

9. All discovery shall be completed by January 15, 2004.

C. OTHER PRE-TRIAL MATTERS

1. All dispositive motions shall be filed no later than January 20, 2004, with opposition papers to be filed and served no later than 30 days after receipt of each motion. Reply papers, if any, shall be filed and served no later than 10 days thereafter.

2. All pretrial motions, including motions in limine regarding the admissibility of expert testimony, shall be filed and served in sufficient time to permit hearing thereon no later than February 20, 2004. Motions in limine shall be filed and served seven working days before trial and responses thereto shall be filed and served five working days before trial. Motions filed in violation of this order will not be considered unless good cause is shown.

3. Counsel for the parties shall file in the record and serve upon their opponents a list of all witnesses who may or will be called to testify at trial and all exhibits that may or will be used at trial no later than February 9, 2004.

D. SETTLEMENT DISCUSSIONS

The parties have had settlement discussions but have not reached any agreement. Counsel for the parties have scheduled a meeting for July 21, 2003 to further discuss possible settlement.

E. TRIAL

Trial is set in this matter on _____, at _____.

F. STATUS HEARINGS

A further status hearing/preliminary pretrial conference will be held on _____ _____, at _____.

Dated: July 18, 2003

/s/
A. Tony Heper
(signed by Michele R. Kendus with permission by A. Tony Heper)

Federal Bar No. 10175
Law Offices of A. Tony Heper
5301 Eastern Ave.
Baltimore, Maryland 21224
410-633-8300
410-633-6347 (fax)

Counsel for Plaintiff Debby L. Otte

/s/
Michele R. Kendus

Federal Bar No. 26586
Venable, Baetjer and Howard, LLP
1800 Mercantile Bank & Trust Building
2 Hopkins Plaza
Baltimore, Maryland 21201
410-244-7400
410-244-7742 (fax)

Michael J. Philippi
Stacey Feeley Cavanagh
Kathleen Holper Champagne
Ungaretti & Harris
3500 Three First National Plaza
Chicago, Illinois 60602
312-977-4400
312-977-4405 (fax)

Counsel for Defendants Baxter Healthcare Corporation and Allegiance Healthcare Corporation

ADDENDUM

LATEX ALLERGY LITIGATION OVERVIEW

A. Natural Rubber Latex Gloves

Natural rubber latex gloves (sometimes NRL gloves) are used by millions of healthcare workers each year to defend against viruses and diseases such as HIV and hepatitis. Natural rubber latex is viewed as a material of choice for medical gloves because of its strong barrier qualities and tactile sensitivity.

Healthcare workers have been using natural rubber latex gloves for decades. NRL is derived from the sap of the rubber tree whose scientific name is hevea brasiliensis. It is ubiquitous, both in medical and non-medical environments. It has been estimated that there are up to 40,000 different consumer products that contain NRL, including condoms, toys, tires, rubber bands, rubber balls, balloons, household and gardening gloves, pacifiers, racket handles, and sporting equipment.

In 1987, due to increased concerns over AIDS and Hepatitis B, the Centers for Disease Control ("CDC") officially recognized the need for high quality barrier protection for healthcare workers and their patients to control the spread of these and other infectious diseases and blood-borne pathogens through a set of guidelines called Universal Precautions. OSHA implemented these guidelines by requiring the use of gloves made of material with the barrier protection qualities of NRL whenever a healthcare worker comes into physical contact with a patient or handles bodily fluids. This practice of "gloving" was mandatory.

In approximately 1989, the FDA began receiving reports regarding possible NRL allergic reactions. As a result, on March 29, 1991, the FDA Commissioner's Office issued a Medical Alert to over one million healthcare workers and professionals in the U.S. referring to the increased reports of allergic reactions to NRL-containing medical devices and to reports of latex sensitivity in the medical literature. The FDA advised these healthcare professionals to identify their latex sensitive patients and be ready to treat allergic reactions promptly. Shortly after sending out this Medical Alert on March 29, 1991, the FDA circulated virtually the same information in its July, 1991 Medical Bulletin. The Bulletin was sent to over one million hospitals, doctors, nurses and other healthcare professionals. These recipients in turn re-copied these alerts and increased the circulation exponentially.

B. Allergy

The immune process (by which one acquires an allergy) and the spectrum of allergic symptoms is the same for all allergens whether they are fruit or pollen or grass or NRL or anything else. Therefore, it is appropriate to begin with an overview of allergy albeit with this caution: Allergy is a complex subject, every individual is unique and the state of knowledge is constantly evolving. The following is a brief overview.

1. IgE antibody - The immune cells responsible for Type I allergy

The immune system protects us from disease by creating antibodies which fight off and kill viruses and bacteria and other foreign (non-self) substances. The antibodies involved in allergy are called IgE antibodies. It is paradoxical that IgE, an antibody of the immune system designed to protect us, should be responsible for allergy. In evolutionary history, IgE antibodies developed as a specialist to fight worms and other parasites that found their way into the human body. In developed countries, where parasites have been virtually eliminated, IgE antibodies unfortunately turned to mischief, that is, causing allergy. In undeveloped countries, where IgE antibodies are still busy protecting humans against parasites, there is coincidentally very little allergy.

2. From sensitization to allergy

A process called "sensitization" must take place before one can become allergic (that is, express allergic symptoms). It is complex and beyond the scope of this overview. If sensitization occurs it results in the proliferation of IgE (immunoglobulin E) antibodies. Sensitization can be defined for our purposes as the presence of IgE antibodies specific to a particular allergen in a human's blood, as measured either by positive skin prick test or positive blood serum test.

It may take one or more re-exposures by the individual to the same allergen before sensitization occurs. It should be noted, however, that most humans are exposed to many kinds of allergens on a daily basis, yet never become sensitized. Even with the small percentage of humans who do become sensitized, the number of re-exposures before sensitization occurs varies, and there is no known threshold for sensitization to allergens. Moreover, many humans, despite being "sensitized" to an allergen (that is, having IgE specific to that allergen present in their blood), will never have an allergic reaction. However, a small percentage of humans, once sensitization occurs, may thereafter experience an allergic reaction after re-exposure to the allergen. That person is considered to have an allergy. Thus, allergy only occurs in humans who are hypersensitive to specific allergens. An allergic reaction can produce a variety of symptoms such as a rash, allergic rhinitis (runny nose), urticaria (hives) asthma and other symptoms. In sum, for "allergy" to occur in a human, there must, first, be exposure to an allergen; there must, second, be production of IgE specific to that allergen in the human's blood, and there must, third, be an allergic reaction by the human to a subsequent exposure to that allergen.

3. Type I allergy v. Type IV allergy

Allergy is a hypersensitive (super sensitive) immune cell reaction to an otherwise benign or harmless substance. In fact, the type of allergic reaction we are concerned with here is called Immediate Type Hypersensitivity (ITH), Type I Hypersensitivity or IgE mediated hypersensitivity. The substances causing ITH for the most part are proteins such as those in dog dander or pollen. Not all proteins in dog dander or pollen or any other substance are capable of causing allergy. Allergenic proteins derived from plants and trees vary in their allergenicity depending, *inter alia*, on the season and growing conditions (*i.e.* amount of water). Most people

won't react to allergens at all. A person can be allergic to one allergen and not to others. It is well recognized that allergy has a major genetic component and certain individuals tend to be allergic to many things. These people are called *atopics*.

The allergic symptoms of an ITH or Type I reaction can vary greatly depending upon the individual's susceptibility or predisposition to the specific allergen and the route of exposure (e.g., cutaneous, mucosal or respiratory). Symptoms can range from localized hives (urticaria) to more severe generalized urticaria. More severe reactions may include gastrointestinal and respiratory distress.

Many allergens look somewhat alike to the immune system. Thus, a person may be allergic to one allergen and then be exposed to another similarly configured protein to which they are not allergic, yet the body is fooled by their molecular similarity into reacting. This is known as *cross reactivity*. Some substances which are not allergens or cross-reacting allergens, say an ingredient in food (or a chemical in the air) may trigger a reaction resembling an allergic reaction (*i.e.*, a release of histamine — a substance which causes allergic symptoms). These are known as non-specific (non-allergenic) stimulators.

Besides Immediate Type Hypersensitivity (or Type I IgE mediated hypersensitivity) there are other types of allergy. One is called Delayed Type Hypersensitivity or DTH also known as Type IV hypersensitivity. They derive their names from the time it takes from exposure to reaction. A Type I allergic response usually occurs approximately 20 minutes after exposure whereas a Type IV reaction typically occurs 24-48 hours after exposure. DTH is caused by T cells whereas, as previously noted, ITH (or Type I) is caused by antibodies which are proteins made by B cells. T cells and IgE react to different allergens. The allergic reaction they cause can lead to both similar and distinct allergic symptoms. The Type IV reactions are usually confined to local areas (as compared to the sometimes more systemic Type I reaction) and may include redness, swelling or edema. Poison ivy is a classic example of a Type IV reaction.

There are also different diagnostic tests for the various types of hypersensitivity reactions. In the diagnosis of latex allergy, the first issue is whether individuals are sensitized, and then whether they have allergy at all and, if so, whether it is Type I or Type IV. In these cases, all plaintiffs allege Type I immediate hypersensitivity.

4. Diagnosis of allergy

Diagnosis of allergy depends on positive lab (blood or *in vitro*) or skin (*in vivo*) testing for sensitization and a thorough history demonstrating verifiable exposure and timely expression of allergic symptoms. Since every person is continuously exposed to allergens from the time of birth, obtaining an accurate exposure history can be difficult. Exposures which do not result in allergic symptoms, including those which may be leading to sensitization, are perceived as harmless non-events and go unnoticed and unremarked. As noted, all ITH allergies cause the same symptoms and many allergic people are atopic meaning that they are genetically predisposed to become allergic, after exposure to allergens. Numerous exposures to allergens occur simultaneously. Further, many symptoms that humans experience are non-specific to

allergy further complicating diagnosis. The tests for sensitization are also subject to false positive and negative results. False positives can be caused, among other things, by cross-reactions.

C. Latex Allergies

Healthcare workers have reported two types of reactions to latex gloves which are unrelated to natural rubber proteins. The first type of reaction is irritant contact dermatitis (sometimes caused by constant hand washing) which is a non-allergic reaction that does not involve cells of the immune system. The second type of reaction is, as discussed above, allergic contact dermatitis or Type IV delayed hypersensitivity and refers to a local allergic reaction (similar to poison ivy) to the chemicals used in the manufacturing process. Both of these reactions can be confused with ITH skin symptoms.

D. NRL Glove Litigation

The first product liability case alleging NRL allergy resulting from the use of NRL medical gloves was filed in or about 1991. Since that date, there have been hundreds of state and federal latex glove lawsuits filed.

The plaintiffs in these cases claim that they have developed NRL allergies from exposure to NRL medical gloves (or, more particularly, to certain potentially allergenic latex proteins in the gloves). Plaintiffs typically allege that, over time, they first become sensitized to NRL as a result of repeated exposure to NRL gloves. They also claim that they then experience allergic reactions on subsequent re-exposure to NRL gloves or other NRL products. In one case a plaintiff, who had never had a reaction to latex gloves alleged that an allergic reaction to a nectarine was really a "cross-reaction" to NRL. (*Bruggencate* identified in the chart *infra*). Some plaintiffs allege that they are so allergic to NRL that they can no longer work in the healthcare field due to the widespread use of NRL gloves and other latex products. Other plaintiffs have continued to work in healthcare, using non NRL gloves, glove liners, or other accommodations. There are also allegations by some plaintiffs that as a result of their NRL allergy, they must avoid common household NRL-containing products and be vigilant for NRL products when they leave their homes.

Plaintiffs variously allege manufacturing and design defects and failure to warn theories. The defendant typically assert the following defenses: plaintiff does not have Type I NRL allergy; lack of general causation (i.e., that any exposure to NRL gloves caused injury to the plaintiff); lack of specific causation (which is the probability that the exposure to a particular defendant's gloves caused injury to the individual plaintiff); lack of product defect; education of healthcare workers regarding NRL allergies; assumption of the risk; comparative negligence; statute of limitations; state of the art; and, as in other allergies, the sufficiency of the labeling and plaintiffs' knowledge that they were using latex gloves.. Healthcare workers are sophisticated users and consumers of NRL gloves, and information about the perceived, developing latex allergy problem was communicated to them through many sources including FDA bulletins, nurse association communications, medical journals and various task forces formed by hospitals. Healthcare workers were also schooled on recognizing and dealing with NRL allergy because it was also an important element in providing adequate healthcare to patients. Moreover, in dealing with allergy issues, warnings on a product about the possibility of sensitization are not effective (*i.e.* cannot be heeded) because there is nothing that one can do until one knows one is actually allergic.

Trial History

Plaintiff	State	Trial Date	Outcome
Kummel v. Smith & Nephew	NJ	June 1997	Defense verdict
Green, et al. v. Smith & Nephew, et al.	WI	Feb. 1998	Plaintiff Verdict
Bruggencate v. Baxter Healthcare Corporation, et al.	CA	April 2000	Voluntarily Dismissed with Prejudice in mid-trial
McGinnis v. Baxter Healthcare Corporation, et al.	CA	June 2000	Defense JNOV - Affirmed On Appeal
Zarnosky v. Smith & Nephew	NJ	September 2000	Defense Verdict
Goolsby v. Baxter Healthcare Corporation	TX	March 2001	Plaintiff Verdict
Turacy v. Tradex Int'l., Inc.	OH	May 2001	Defense verdict
Gonoude v. Baxter Healthcare Corporation, et al.	PA	May 2001	Settled at Trial
Falcone v. Safeskin Corporation	PA	September 2001	Plaintiff Verdict
Steffen v. Johnson & Johnson, et al.	TX	October 2001	Defense Verdict

Langlois and Borazzas (consolidated)	NH	March 2002	Defense Verdict (Both)
Kennedy v. Baxter Healthcare Corporation, et al.	MN	April 2002	Defense Verdict
Patzek v. Aladan Corporation, et al.	PA	July 2002	Defense Verdict
Rourke-Nichols v. Baxter Healthcare Corporation, et al.	CA	October 2002	Defense verdict
Gilberti v. Touro Infirmary, et al.	LA	February 2003	Defense verdict

As of March 1, 2003, there have been a total of sixteen (16) cases that have started trial. One case was settled during trial, one was dismissed by plaintiff after several trial days with no payment and there were fourteen (14) dispositions by jury verdict. One jury verdict for the plaintiffs was vacated by JNOV and affirmed on appeal. The current tally is eleven (11) dispositions in favor of the defense and three (3) for plaintiffs. The last seven (7) trials have resulted in defense verdicts.